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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,755	10/19/2004	Gregory Pipko	1361-US	4845
24505	7590	06/27/2006	EXAMINER	
DANIEL J SWIRSKY 55 REUVEN ST. BEIT SHEMESH, 99544 ISRAEL			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,755

Applicant(s)

PIPKO ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement is made of Applicant's newly amended claims 11-15 and 17-19, new claims 20 and 21 and cancelled claims 1-10 and 16 received on 6 April 2006.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-15 and 17-21 are pending in this Application.

Claims 11-15 and 17-21 are under examination.

Claim Objections

Newly applied as necessitated by amendment.

Newly amended Claims 11-15 and 17-19 are objected to because of the following informalities: the term "non-phytotoxicity", in claim 11, line 1, should be corrected to read non-phytoxic and the term "crop", in Claim 11, line 2, should be corrected to read "crops". Appropriate correction is required.

Newly amended Claim 19 is objected to because of the following informalities: the term "saturated fatty acid", in line 5, should be corrected to read saturated fatty acids, the term "agroup", in line 5 and line 9, should be corrected to read a group and the term "lignoceric" should be removed from line 10, since it is not an unsaturated fatty acid. Appropriate correction is required.

Newly amended Claim 21 is objected to because of the following informalities: the term "pathogans", in claim 21, line 1, should be corrected to read pathogens. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly amended Claims 11-15 and 17-21 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Newly applied as necessitated by amendment. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims as set forth in the amendment filed on 6 April 2006 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the instant case, original Claim 11 did not disclose a non-phytotoxicity emulsion, wherein Applicant claimed, as Claim 11, "Fungicidal emulsion comprising tea tree oil and water emulsion wherein the emulsifier is a water solution of a reaction product of a high molecular weight organic fatty acid and an alkali or ammonium compound", whereas in amended Claim 11, Applicant claims, "A non-phytotoxicity emulsion for use in agriculture crop, especially for treating fungal disease, comprising tea tree oil in emulsion of alkali or ammonium salts of organic fatty acids", thereby introducing a new description of the emulsion, which

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is not disclosed in either the Specification or the original Claims, and is considered to be new matter. Insertion of the above mentioned claim limitations have no support in the as-filed specification. The insertion of the limitations are new concepts because they neither have literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the new limitation which would show possession of the concept for a non-phytotoxicity emulsion for use in agriculture crop, especially for treating fungal disease, comprising tea tree oil in emulsion of alkali or ammonium salts of organic fatty acids. Furthermore, there are no examples wherein a non-phytotoxicity emulsion is provided, however, in paragraph 0004 of the Specification, Applicant discloses, "It has been shown that tea tree oil inhibits certain fungi (See for example Australian Journal of Experimental Agriculture 39:1, 86-81, 1999). The treatment was satisfactory as it killed the fungi to a large extent, and mainly fungi that attack human, while in plants it caused phytotoxicity to attacked plants", which appears to be a contradiction of amended Claim 11. This is a matter of written description, not a question of what one of skill in the art would or would not have known.

The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

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As the above- mentioned claim limitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended Claims 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 19 are rendered uncertain by the phrase "at least one portion of" in lines 3, 5 and 9 because the phrase "at least one portion" could refer to one portion of the composition or an amount of tall oils, naftenic acids or rosin acids (line 3), saturated fatty acids (line 5) or unsaturated fatty acid (line 9). The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 21 recites the following limitations: "said pathogans" in line 1 and "the flowers, fruits, leaves, roots, tubers, bulbs or any other plant matter" in line 2. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

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Claims 11-13, 17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hyldgaard (A*). The rejection is maintained for the reasons set forth in the previous Office Action and for the reasons set forth below.

Applicant argues Hyldgaard teaches an oil-in-water emulsion for application on a skin surface and that Hyldgaard further teaches protection of skin against sun light and with respect to combating attack from parasites like lice, fleas and scabies on mammals such as humans, domestic animals and pets. Applicant further argues that the protective layer taught by Hyldgaard may protect human skin or animal skin **but is definitely toxic to plant's epidermis and pores** (Emphasis added by Applicant). Applicant further teaches that anti-fungal properties of tea tree oil are known in the art, however, **the significant phytotoxicity has to date prevented its commercial use in agriculture** (Emphasis added by Applicant) and Applicant further cites Washington et al. in 1999 in the Australian Journal of Experimental Agriculture (39:1, pp 81-86), wherein tea tree oil mainly inhibits fungi that attack human and for infected plants it is phytotoxic (Emphasis added by Applicant). Applicant further argues that Applicant's invention shows an inventive step because of the non-phytotoxicity feature of the tea tree oil emulsion and that this "unique" feature enables the introduction of tea tree oil, along with its fungicidal activity to disinfection agricultural crops. Applicant's arguments have been fully considered but they are not persuasive for the reasons set forth in the previous Office Action and for the reasons set forth below.

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Hyldgaard teaches an oil-in-water emulsion comprising an oily phase and an aqueous phase (column 39, claim 1). Hyldgaard further teaches an oil-in-water emulsion comprising myristic acid, lauric acid, palmitic acid, stearic acid, arachindic acid, behenic acid, undecylenic acid and lignoceric acid, and mixtures thereof (column 10, lines 33-50 and columns 39 and 40, claims 9 and 10), palamitoleic acid, oleic acid, linoleic acid and mixtures thereof (column 10, lines 33-50 and columns 39 and 40, claims 9 and 10), and sorbic acid (column 18, lines 16-22). Hyldgaard further teaches the oil-in-water emulsion further comprising tall oil fatty acid (column 14, lines 24-25 and 33-36 and column 40, line 17), sodium, potassium and ammonium salts (column 10, lines 21-32), more specifically sodium hydroxide (column 9, lines 43-54) and potassium hydroxide (column 28, lines 27 and 38), tea tree oil (column 18, lines 49-50 and column 19, lines 39-40), eucalyptus extract (column 18, lines 49-50 and column 19, lines 6-7), lavender extract (column 18, lines 49-50 and column 19, line 21), lemon extract (column 18, lines 49-50 and column 19, line 22), pine needle extract (column 18, lines 49-50 and column 19, line 31), rosemary extract (column 18, lines 49-50 and column 19, line 35). Hyldgaard further teaches an oil-in-water emulsion, wherein the oily phase constitutes not more than 50% w/w of the total emulsion in a range of 1-50% w/w, such as about 5-40% w/w and 10-30% w/w (column 13, lines 55-58). Hyldgaard does not specifically teach that the oil-in-water emulsion is a fungicide nor does Hyldgaard teach that the emulsion is characterized by fungicide activity for treating plants, crop and soil diseases, however, the claimed functional properties are inherent to the preparation taught

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by Hyldgaard because the ingredients taught by Hyldgaard are one in the same as disclosed in the instantly claimed invention of Applicant. Hyldgaard also does not teach using an oil-in-water emulsion on agricultural crops. However, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims. In response to Applicant's argument that the oil-in-water emulsion taught by Hyldgaard does not provide the "unique" non-phytotoxicity feature provided by the tea tree oil emulsion in Claim 11, please note that the term "unique" is a relative term and that the term "unique" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of an "unique" and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Furthermore, since the Patent Office

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does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, The Office cannot determine whether Applicant's invention has a "unique" effect not disclosed in Hyldgaard. Particularly since Hyldgaard appears to teach the same composition as claimed by Applicant and provides the same range of amounts of the active components.

Claim Rejections - 35 USC § 103

Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyldgaard (A*), in view of Saleh et al. (B*), Lawless (U*) and Morris et al. (V). Newly applied as necessitated by amendment.

Applicant argues that Saleh teaches a multipurpose skin preparation in the form of an oil-in-water emulsion, which leaves behind a protective layer and which prevents the use of the cited emulsion in plants. Applicant further argues that neither Hyldgaard nor Saleh show or suggest non-phytotoxic characteristics of the emulsion and its use in agriculture and that it is not obvious to one of ordinary skill in the art to modify these emulsions taught by Hyldgaard and Saleh to obtain a non-phytotoxic effect and that these emulsions are not non-toxic vehicle tea tree oil. Applicant further argues that despite Lawless' teachings of antifungal, antibacterial and antiviral properties, that the strong phytotoxic property of tea tree oil avoids its use in agriculture. Applicant further argues that none of the combinations of Hyldgaard, Saleh and Lawless would be useful in treating agricultural crops, the use of free acids is not inherent to either

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Hyldgaard or Saleh and that the ranges taught by Hyldgaard and Saleh do not anticipated the range claimed by Applicant.

The teachings of Hyldgaard are set forth above and applied as before. Hyldgaard further teaches an oil-in-water emulsion, wherein the oily phase constitutes not more than 50% w/w of the total emulsion in a range of 1-50% w/w, such as about 5-40% w/w and 10-30% w/w (column 13, lines 55-58).

Saleh teaches a multipurpose skin preparation in the form of an oil-in-water emulsion by combining an oil phase and an aqueous phase, wherein the oil phase contains stearic acid (column 6, lines 19-20 and lines 35-42), lavender oil (column 10, lines 16-43) and other adjunct ingredients, such as tea tree oil, which are anti-bacterial agents and anti-fungal agents (column 7, lines 42-47 and lines 56-64). Saleh further teaches that tea tree oil is believed to aid as an antibacterial and antiseptic (column 7, lines 42-47 and lines 56-64). Saleh further teaches that tea tree oil is present in a range from about 0.001% to about 4% by weight of the total skin preparation and preferably in the amount of about 0.02% by weight (column 7, lines 56-64).

Lawless teaches tea tree oil has antifungal, antibacterial and antiviral properties.

Morris teaches an antimicrobial composition for treating fungal, viral and bacterial infections in animals, humans and plants (which reads on other plant matter) as a crop treatment comprising tea tree oil, lavender oil, eucalyptus oil and clove oil, wherein the composition is non-toxic and does not harm plants when used as a crop treatment.

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The teachings of Hyldgaard, Saleh, Lawless and Morris are set forth above. Hyldgaard does not teach a concentration of tea tree oil between 0.01 and 10% nor does Hyldgaard teach a concentration of tea tree oil between 0.1 and 1.5% nor does Hyldgaard teach a concentration of tea tree oil between 0.1 and 1.5%, wherein the concentration of the product is 0.1% to 1% and further wherein the remainder being water nor does Hyldgaard teach a composition for treating crops, wherein pathogens are located in flowers, fruit, leaves, roots, tubers, bulbs or any other plant matter. However, it would have been obvious to one of ordinary skill in the art and one would have been motivated and one would have had a reasonable expectation of success to modify the oil-in-water emulsions taught by Hyldgaard to provide the instantly claimed invention because at the time the invention was made, the bioactive effects of tea tree oil, particularly as an fungicidal agent were well known in the art, as clearly taught by Saleh and Lawless and tea tree oil was known to treat fungal, viral and bacterial infections in humans, animals and plants, as a crop treatment. Therefore, it would have been obvious to one of ordinary skill in the art to adjust the amounts of tea tree oil in a composition taught by Hyldgaard to treat fungal infections, viral infections and bacterial infections in humans and plants to provide the instantly claimed invention because at the time the invention was made an antimicrobial composition comprising tea tree oil was known as clearly taught by Saleh, as was a composition comprising tea tree oil to treat fungal infections, viral infections and bacterial infections in humans and plants, as clearly taught by Morris.

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Furthermore, as the references indicate, the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables and would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references particularly since the result-effective adjustment of particular conventional working conditions (e.g., adjusting the amount of bioactive agents in a composition, such as tea tree oil, to treat fungal, viral or bacterial infections) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a concentration of tea tree oil and the concentration of the product and the percentage amounts of the ingredients thereof to provide an emulsion comprising tea tree oil and water emulsion wherein the emulsifier is a water solution of a reaction product of high molecular weight organic fatty acid and an alkali or ammonium compound, as taught by Hyldgaard and Saleh. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Based upon the beneficial teachings of the cited reference, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

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Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
June 16, 2006


MICHELE FLOOD
PRIMARY EXAMINER